

公司认证

Company Certification



Certificate of Registration

The Governing Board of
INTERNATIONAL STANDARDS CERTIFICATION LIMITED
hereby grants to:

Nanning TECBOD Biological Technology Co.,Ltd.

Address: Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning , Guangxi,
P.R.China

Has been assessed and found to be in accordance with the requirements of
standard detailed below

ISO 13485:2016

Scope

Production and Sales of Medical Devices
(see attachment for products included)

Authorized by: Blena YP-KO



Certificate No.:ISC3485202033042

Initial Certificate Date:2020-03-18 Certificate Expiration Date:2023-03-17

Note: The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, the certified clients shall accept regular surveillance audit, the validity of certificates shall be maintained for the positive result of audit.



INTERNATIONAL STANDARDS
CERTIFICATION LIMITED
ROOM 22,13 F,SPEEDY INDUSTRIAL BUILDING,
114 HOW MING STREET,KOWLOON,HONG KONG
Email:info@accredititservice.com
Check the validity of certificate at
www.accredititservice.com



INTERNATIONAL STANDARDS CERTIFICATION LIMITED

Attachment to Certificate

Certificate No.:ISC3485202033042

Organization:

Nanning TECBOD Biological Technology Co.,Ltd.
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao,
Nanning , Guangxi, P.R.China

Scope

Products:

Medical Protective Clothing
Disposable isolation gown
Single-use medical protective overboot
Single-use medical protective hood
Clean air suits
Reusable surgical drapes
Surgical gowns
Single-use surgical gowns
Disposable medical protective bag
Surgical cap
Wash clothes
Medical pads
Medical face-shield
Medical goggle
Latex Examination Gloves

Authorized by: Blena YP-KO

Initial Certificate Date:2020-03-18 Certificate Expiration Date:2023-03-17



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CE符合性声明

CE Declaration of Conformity

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300406

Name und Adresse des Herstellers: /
Name and address of the manufacturer:

Nanning TECBOD Biological Technology Co., Ltd.
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning ,
Guangxi, P.R.China

Bevollmächtigter der EG: /
EC Authorized Representative:

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt: /
the medical device:

Einweg-Isolationskleid / Disposable isolation gown
Modell/ Model: Conjoined coverall/M, L, XL, XXL, XXXL(Full body)
Split overalls/XS, S, M, L, XL, XXL
11901

Produktfotografie: / Product photograph:



Grundlegende UDI-DI: / Basic UDI-DI:

/

Handelsname: / Trade name:

/

der Klasse: / of class:

Class I

nach Anhang VIII der Verordnung EU 2017/745 (MDR) /
according to annex VIII of Regulation EU 2017/745(MDR)

Erfüllt die Bestimmungen der Verordnung EU 2017/745 (MDR). Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. / Meets the provisions of the Regulation EU 2017/745(MDR). The declaration is valid in connection with the "final inspection report" of the device.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure:

Annex II, Annex III of EU 2017/745

Die Konformitätserklärung ist gültig bis: /
Declaration of Conformity is valid until: /

2021-03-24

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)

| Klasse / Class | | |
|---|----------|-----------|
| I | | |
| I - steril / sterile | | |
| I - mit Messfunktion / with measuring function | | |
| I - steril und mit Messfunktion / sterile and with measuring function | | |
| IIa | | |
| IIb | | |
| III | | |
| III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 | | |
| manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 | | |
| Aktives implantierbares Medizinprodukt / Active implantable medical device | | |
| Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 | | |
| Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 | | |
| App (Software auf mobilen Endgeräten) | ja / yes | nein / no |
| Nummer(n) der Bescheinigung(en) / Certificate number(s) | | |
| Handelsname des Produktes / Trade name of the device | | |
| Disposable isolation gown | | |
| Produktbezeichnung / Name of device | | |
| Conjoined coverall/M, L, XL, XXL, XXXL (Full body); Split overalls/XS, S, M, L, XL, XXL | | |
| Nomenklaturcode / Nomenclature code | | |
| 15-037 | | |
| Nomenklaturbezeichnung / Nomenclature term | | |
| Kleidung, Isolation | | |
| Kategoriecode / Category code | | |
| 10 | | |
| Kategorie / Category | | |
| Produkte zum Einmalgebrauch | | |
| Kurzbeschreibung deutsch / German short description | | |
| Kurzbeschreibung englisch / English short description | | |

Nanning 2020-03-25

雷珍
Leizhen General manager

Ort, Datum / Place, date /

欧盟授权代表协议

MDR EU REP Agreement

EU Authorized Representative Agreement

NO. 20200325Z-5

This European Authorized Representative Agreement is signed on Mar 25, 2020, between Llins Service & Consulting GmbH, located at Obere Seegasse 34/2, 69124 Heidelberg, Germany (hereinafter referred to as "Llins", DIMDI Code DE/0000048234), and Nanning TECBOD Biological Technology Co.,Ltd, located at Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning , Guangxi, P.R.China (hereinafter referred to as "Manufacturer").

Manufacturer hereby appoints Llins as the European Authorized Representative for their Medical Device with CE mark to provide authorized representation services as required per Regulation (EU) 2017/745 where applicable, the appointed product categories are set out in Appendix A.

Hereafter when reference is made to the EU, this is meant to include the EEA, Switzerland and Turkey.

Llins shall provide the relevant service as stipulated herein as the authorized representative of the Manufacturer.

Llins accepts the appointment to be the authorized European Representative for the Manufacturer in EU. Both parties enter this agreement as below:

A. Obligations and Liabilities

I. Llins

1. Llins shall apply requirements with competent authority in accordance with Article 11, Article 12, Article 15, Article 30, Article 31, Article 60 of Regulation (EU) 2017/745.
2. Llins shall comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29. Additional charges may apply for product registration.
3. Llins shall reserve the technical documentation of each category of Manufacturer's products with CE mark, and take up the responsibilities of keeping custody and confidentiality and submission upon the request of the competent authority. The technical documentation shall be reserved at least fifteen years after the phase-out production. Once the technical documentation (including new version of the technical documentation which had already been filed) of each category of Manufacturer's products with CE mark is requested by the competent authority, Llins shall submit within ten working days upon the receipt of relevant documents.
4. Llins shall forward to the manufacturer any request by Regional Council Karlsruhe for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device.
5. Llins shall cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.
6. Llins shall immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which Llins has been designated.

1 / 8
Ren
28.03.2020

Version 1.0, effective date 31.01.2020

(Appendix A)

List of products applying for CE mark:

| No | CE certificate number (if applicable) | CE certificate valid date (if applicable) | Product name | Models | UMDNS / EDMS | Device Class |
|----|---------------------------------------|---|--|--|--------------|--------------|
| 1 | NA | NA | Single-use medical protective overboot | Normal type/ L(30cm~40cm)*W(10cm~30cm) Tall type/ L(30cm~40cm)*W(10cm~30cm)*H(30cm~60cm) | | I |
| 2 | NA | NA | Disposable isolation gown | Conjoined coverall/M, L, XL, XXL, XXXL (Full body) Split overalls/XS, S, M, L, XL, XXL | 15037 | I |
| 3 | NA | NA | Medical Protective Clothing | Conjoined coverall/XS, S, M, L, XL, XXL Split overalls/XS, S, M, L, XL, XXL | 11901 | I |

The detailed arrangements for a change of authorized representative:

Applicable

The date of termination of the mandate of the outgoing authorized representative: _____

Not Applicable

Note:

Manufacturer shall confirm that there is only one Authorized Representative for all devices of the same generic device group.

This EU Authorized Representative agreement is valid from until 2025.03.25.

Llins Service & Consulting GmbH
Obere Seegasse 34/2
69124 Heidelberg

北京有限公司
37

6 / 8

Ren
28.03.2020

FDA注册注明

FDA registration confirmation

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

NANNING TECBOD BIOLOGICAL TECHNOLOGY CO., LTD
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao Nanning,
Guangxi, 530033, CHINA

The facility registration and device listing information:

| Owner/Operator Number: 10067979 | | |
|---------------------------------|--------------|---|
| Device Listing No. | Product Code | Product Name(s) |
| D387308 | OEA | Protective clothing, Isolation Gown,Clean air suits |
| D387311 | HOY | Medical goggle |
| D387327 | FXP | Shoe cover |
| D387331 | LYU | Glove |
| D387333 | FYE | Disposable surgical gown,surgical gown |
| D387334 | KPY | Face-Shield |
| D387337 | FYF | Medical cap |

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2007US233518
Issue date: Apr.08, 2020

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com



产品信息

product information

| 产品名称 | 规格型号 | 执行标准 | 国际认证 | 日产量 | 功能特点 | 用途 | 材质 | 装箱规格 | 外箱尺寸 | 净重/毛重 |
|----------|-----------|---------|-----------------------------------|-----|---------------|-----------------------|------------------------------------|-------|------------------|--------------------|
| 一次性医用隔离衣 | 全连身式 XXXL | EN14126 | ISO13485:2016 CE符合性声明 FDA注册 | 6万件 | 防水、阻菌、透湿、全身防护 | 用于医疗机构门诊、病房、检验室等作普通隔离 | SF无纺布 70-75克/ m ² | 50件/箱 | 80*40* 52(cm) | 11.6kg / 13.6kg |

| Product name | Models & Specifications | Execution standard | International certification | Daily output | Functional features | Application scope | The material | Packing specification | Carton size | NW/GW |
|---------------------------|-------------------------|--------------------|--|---------------|--|--|--|-----------------------|--------------|-----------------|
| Disposable isolation gown | Full body type, XXXL | EN14126 | ISO13485:2016 CE Declaration of Conformity FDA | 60,000 pieces | Waterproof, bacteriostatic, moisture permeable, full body protection | Used for general isolation in out-patient, ward and laboratory of medical institution. | SF, non-woven fabric ; 70-75g/m ² | 50 pieces/carton | 80*40*52(cm) | 11.6kg / 13.6kg |